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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,600	05/16/2007	Alfred Niederberger	10139/08802	1693
76960	7590	01/03/2011		
Fay Kaplun & Marcin, LLP 150 Broadway, suite 702 New York, NY 10038			EXAMINER LAWSON, MATTHEW JAMES	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 01/03/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/593,600

**Applicant(s)**

NIEDERBERGER ET AL.

**Examiner**

MATTHEW LAWSON

**Art Unit**

3775

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 12, 14 and 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14, 16-21 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12, 14, 16-19, and 21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Macchia (US 3,054,321) in view of Landry (US 2004/0143265) in further view of Takachi (US 6,470,767).

Regarding claims 11, 14, 16, 18, and 21 Macchia discloses a bone screw comprising: a head (26), and a shaft extending distally from the head (figures 1-2, 10) and having a longitudinal axis, the shaft further comprising a proximal section (see figure below) adjoining the head and having a second outer diameter smaller than the first outer diameter (figures 1-2, 10), an outer wall of the proximal section being at least partially threaded (34, figure 1), and a distal section (see figure below) extending distally from the proximal section and being attached to the proximal section by way of a ball (40)-and-socket (30a) joint (figures 1-2, 10), wherein the distal section is at least partially threaded (figures 1-2, 10) and the length of the shaft is constant (figures 1-2, 10), and the distal section is allowed to deflect no more than about 90 degrees relative to the longitudinal axis (figures 1-2, 10) and the distal section is rotatable relative to the proximal section about the longitudinal axis (column 2, lines 66-67) and the ball-and-socket joint includes a ball in contact with one of the proximal section and the distal

section (figures 1-2).

Macchia fails to disclose the shaft being cannulated.

Landry et al. disclose a cannulated shaft (114, figure 6) to be used with a guide wire so that the shaft may be inserted into a vertebra at a desired location and in a desired angular orientation relative to the vertebra with limited or no visibility of the vertebrae (§126). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the screw of Macchia to be cannulated so that a guide wire could be used permitting for insertion and alignment with limited or no visibility of the surgical site as taught by Landry.

Macchia further fails to disclose the head being spherical or cylindrical (having a first diameter) rather Macchia teaches a hexagonal head.

Macchia discloses the claimed invention except that the head is hexagonal instead of spherical. Takachi (US 6,470,767) shows that a hexagonal head is an equivalent structure known in the art (column 3, lines 34-37). Therefore, because these two screw heads were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the hexagonal head for the spherical head of Takachi.

Regarding claim 12, Macchia discloses the claimed invention except for the distal section comprising the socket portion of the connection and the proximal section comprising the ball portion of the ball-and-socket connection. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to have the ball portion be on the distal section and the socket portion of the proximal section since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Regarding claim 17, Macchia discloses the claimed invention except for the proximal section having a larger diameter than the distal section. It would have been an obvious matter of design choice to have the distal section smaller than the proximal section, since applicant has not disclosed that the difference in diameters between the two sections solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a proximal diameter that is equal or slightly smaller than the distal section.

With regard to claim 19, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone screw of the combination of Macchia as modified by Landry and Takachi to deflect no more than about 30 degrees relative to the longitudinal axis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macchia (US 3,054,321) in view of Landry (US 2004/0143265).

Macchia discloses a bone screw comprising; a head (26), a shaft extending distally from the head and having a longitudinal axis, a proximal section (see figure below) adjoining the head wherein the proximal section is at least partially threaded (34), and a distal section (see figure below) polyaxially associated with the proximal section (figures 1-2, 8, and 10), the distal section being separated from the head by the proximal section (figures 1-2) and the ball-and-socket joint includes a ball in contact with one of the proximal section and the distal section (figures 1-2).

Macchia fails to disclose the shaft being cannulated.

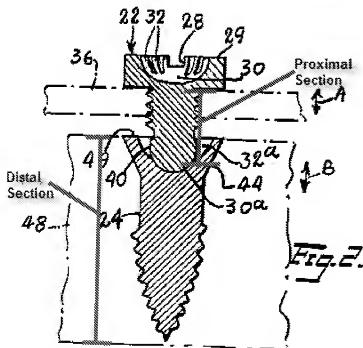
Landry et al. disclose a cannulated shaft (114, figure 6) to be used with a guide wire so that the shaft may be inserted into a vertebra at a desired location and in a desired angular orientation relative to the vertebra with limited or no visibility of the vertebrae (§126). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the screw of Macchia to be cannulated so that a guide wire could be used permitting for insertion and alignment with limited or no visibility of the surgical site as taught by Landry.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macchia (US 3,054,321) in view of Landry (US 2004/0143265) in view of Takachi (US 6,470,767) in further view of Purcell et al. (US 2004/0236330).

Macchia in view of Landry in view of Takachi disclose the claimed invention except for the ball having an octagonal shape.

Purcell et al. disclose a bone screw comprising a head, a shaft having a

longitudinal axis, a proximal section adjoining the head, and a distal section; wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (abstract), wherein the ball has a substantially octagonal shape (figures 12-13, ¶139) to permit a variable angular relationship between the two portions (¶139). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Macchia to have a ball with an octagonal shape as taught by Purcell et al. to permit a variable angle relationship between the two portions of the bone screw.



### ***Response to Arguments***

Applicant's arguments filed 18<sup>th</sup> November 2010 have been fully considered but they are not persuasive.

The Applicant's argue that it would be inappropriate as a terminological manner to regard the head portion 44 of Macchia as a portion of the shaft because Macchia treats the two segments of his fastener as two individual bone screws with respective heads 44 and 26, shafts 22 and 20 and a single mating tip 40. The Examiner respectfully disagrees. It is within reason for the Examiner to interpret the entire screw assembly of Macchia as a single entity. As claimed the device of Macchia anticipates the claimed structure of the Applicant's invention, but does so by using different terminology for the various structural features.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. L./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775